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TO RUEHC/SECSTATE WASHDC PRIORITY 2509
INFO RUCNASE/ASEAN MEMBER COLLECTIVE
RUEHGV/USMISSION GENEVA 0843
RUEHC/DEPT OF LABOR WASHDC
RUCPDOC/DEPT OF COMMERCE WASHDC
RUEATRS/DEPT OF TREASURY WASHDC

UNCLAS SECTION 01 OF 02 SINGAPORE 000371

SIPDIS

C O R R E C T E D C O P Y (ADDED PARA MARKINGS)

SENSITIVE
SIPDIS

STATE FOR EB/IPC, EAP/MTS
STATE PASS TO USTR FOR VESPINEL AND JJENSEN
COMMERCE FOR JBAKER
USPTO FOR PFOWLER
COPYRIGHT OFFICE FOR MPOOR

E.O. 12958: N/A
TAGS: KIPR ECON ETRD EINV USTR WTRO SN
SUBJECT: SINGAPORE 2007 SPECIAL 301 REVIEW: RECOMMEND NO CHANGE IN STATUS

REF: A. STATE 7944

¶B. 06 SINGAPORE 3442

SINGAPORE 00000371 001.2 OF 002

¶1. (SBU) Summary: Post recommends maintaining Singapore's current Special 301 status in 2007, i.e., not on the Watch List. Singapore remains committed to enhancing what is already one of Asia's strongest intellectual property regimes. The government continues to implement its IPR-related commitments under the U.S.-Singapore Free Trade Agreement (FTA), including amendments to its Copyright, Trademarks, and Patents Acts, and a new Optical Disk Act. The Pharmaceutical Research and Manufacturers of America (PhRMA) has cited certain "market access barriers;" We recommend using the annual FTA review mechanism rather than the Special 301 process to address the issues. End Summary.

Parallel Import Regulations

¶2. (SBU) PhRMA voiced concern that Singapore's issuing licenses to import pharmaceuticals from third countries could lead to greater risks of counterfeiting, improper handling, and inadequate or inappropriate packaging. Parallel imports do not contravene Singapore's FTA commitments as described in Article 16.7.2 and Footnote 16.10, which deem parallel imports to be restricted only if the product is not currently sold in the domestic market. Singapore amended its Patents Act to conform to the FTA, and imposes no other restrictions on parallel imports except for certain controlled substances.

¶3. (SBU) Singapore's Health Sciences Authority (HSA) reports that it has received no accounts of counterfeit drugs' entering Singapore through parallel import. Similarly, Post's Immigrations and Customs Enforcement (ICE) office says it is not aware of any specific examples of counterfeits entering via this channel.

¶4. (SBU) HSA maintains strict control of pharmaceutical imports. According to HSA, applicants must provide extensive documentation prior to importation, including:

--A statement from the exporter showing that it is a registered pharmaceuticals dealer in the exporting country;
--Documentation showing that the product is registered in the exporting country;
--An invoice from the exporting agent indicating the batch number of the proposed import;
--A certificate of analysis of the proposed import from the manufacturer or approved laboratory;
--A statement from the company accepting responsibility for the quality, safety, and efficacy of the proposed import;
--Documentation showing compliance with internationally recognized practices throughout the supply chain from source of manufacture to importation;
--Proposed product and locally registered product packaging and labeling; and
--A copy of the company business registration certificate.

Standard Drug List

¶5. (SBU) PhRMA also raised concerns with the transparency of Singapore's Standard Drug List (SDL) process. We do not accept the Ministry of Health's explanation that the fairness of the current process is in part due to the non-involvement of industry, and we will raise the matter with the GOS. While a legitimate market access concern, we believe SDL transparency is an issue that would be more effectively addressed through alternative channels such as our annual FTA review process.

Separation of Prescription and Dispensing Authorities

¶6. (SBU) PhRMA also said it was concerned about Singapore's lack of a required separation of prescription and dispensing authorities (e.g., between physicians and pharmacies). We recommend handling this issue through the FTA review process as well.

Pharmaceutical Investment in Singapore

¶7. (SBU) At the time of its submission, PhRMA could not estimate the damages incurred in 2006 attributable to trade barriers related to intellectual property protection and market access. We also were unable to determine these damages, but note that, according to the Singapore Economic Development Board, more than 20 pharmaceutical companies currently have manufacturing and research and development operations in Singapore. Several U.S. companies have cited the strength of Singapore's IPR laws and enforcement capabilities as a determining factor in their decisions to increase existing investments or commence new operations here since the FTA came into effect in January 2004. According to the Ministry of Trade and Industry, pharmaceutical output, in terms of GDP, has nearly doubled over the last four years to 11 percent. In 2006, investment commitments by PhRMA member-companies Abbott, Merck, and GlaxoSmithKline exceeded US$ 500 million.

¶8. (SBU) We will address septel the "special mention" of Singapore made by the International Intellectual Property Alliance (IIPA).
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